

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT
THERAPY PRODUCTS LIABILITY LITIGATION

This document applies to:
All Cases

MDL No. 2545

Master Docket Case No. 1:14-cv-01748

Honorable Matthew F. Kennelly

**PLAINTIFFS' STEERING COMMITTEE'S RESPONSE TO
BESINS HEALTHCARE INC.'S AND BESINS HEALTHCARE, S.A.'S
STATEMENT OF FACTS**

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Plaintiffs' Co-Lead Counsel *on behalf of* Plaintiffs' Steering Committee

April 20, 2018

Pursuant to Local Rule 56.1, the Plaintiffs' Steering Committee provides the following response to Defendants' Statement of Material Facts in Support of Their Motion for Summary Judgment.

THE PARTIES

1. Admit.
2. Admit.
3. Admit.

VENUE AND JURISDICTION

4. Admit.
5. Admit.

BESINS' STATEMENT OF FACTS

6. Admit.
7. Disputed, given the fact that the Besins defendants attended several in-person meetings and telephone conferences and sat on joint steering committees with AbbVie, during which time AndroGel marketing activities were discussed. Ex. 1, Besins 30(b)(6) Tr. at 28:1-29:24; 34:10-54:13; 59:17-64:4; 83:3-10.

8. Admit.
9. Admit.

10. Disputed. Besins Inc. was primarily "responsible for the relationship with AbbVie in the United States," which included joint AndroGel steering committees and boards. Ex. 2, MacAllister Tr. at 28:1-31:1; 56:8-16. "All aspects of the product," such as patent, supply, sales, and marketing issues, were presented and discussed. *Id.* at 29:12-24.

PLAINTIFF'S STATEMENT OF MATERIAL FACTS

11. Besins S.A. co-developed the pharmaceutical formulation for AndroGel. Ex. 3, Master Answer of Defendant Besins Healthcare, S.A., ¶ 55-56, Master Dkt. No. 1589.

12. Besins S.A. employs staff with responsibility related to the clinical development of AndroGel, staff who are responsible for reporting, investigating, and analyzing spontaneous adverse reactions and/or complaints of side effects related to AndroGel, and staff who are responsible for medical knowledge and/or supervisory medical oversight concerning AndroGel. *See* Ex. 4, Response of Besins Healthcare, S.A. to Plaintiffs' Interrogatories, dated December 12, 2016, ("Besins S.A. Dec. 12, 2016 Interrogatory Responses") at 9.

13. Besins S.A. maintains the worldwide safety database, or "pharmacovigilance file," for AndroGel, which includes all reported adverse events for AndroGel from within the United States and from outside the United States. Ex. 1 at 73:8-18.

14. Besins S.A.'s Pharmacovigilance Department is responsible for the following tasks with respect to AndroGel:

- Collection of all safety information on a product obtained from the published literature, spontaneous case reports or clinical studies;
- Ensure timely expedited reporting of adverse events to the Competent Authorities;
- Continuously evaluate the risk/benefit ratio through signal detection activities;
- Production of Periodic Safety Update Reports (PSURs) for Besins Healthcare products and timely submission to the Competent Authorities;
- Update Risk Management Plans (RMPs) and Company Core Safety Information (CCSI);

- Production and update Safety Data Exchange Agreements (SDEAs) between Besins Healthcare and our partners;
- Answer safety reports received from Licensing Partners, Competent Authorities, other Besins Healthcare Departments, consumer or Healthcare professionals.

Ex. 5 at Besins 000087-000100.

15. Besins S.A.'s Global Safety Committee is responsible for the following tasks with respect to AndroGel:

- Analyzing signals highlighted during signal detection;
- Assessing the risk/benefit ratio of Besins Healthcare products;
- Reviewing of Company Core Safety Information (CCSI) and Risk Management Plans (RMPs).

Id.

16. Besins S.A.'s Global Safety Committee is responsible for signal detection, meaning Besins S.A. assesses whether there are new safety signals associated with Besins' products, including AndroGel. Ex. 6 at Besins 000176.

17. Besins S.A.'s Global Safety Committee is further responsible for determining whether any course of action, such as suspending marketing authorization of a Besins product if required and if so to escalate that to the Global Labeling Committee. Ex. 6 at Besins 000178.

18. Besins S.A. and AbbVie entered a Safety Data Exchange Agreement dated January 28, 2013, which was a "reciprocal agreement where adverse events are exchanged between Abbvie and Besins and between Besins and AbbVie." Ex. 7; Ex. 1 at 71:5-14.

19. The Safety Data Exchange Agreement was entered "for purposes of facilitating accurate, timely exchange of adverse events and each company's compliance with regulatory reporting requirements in each company's territories." Ex. 7 at I.

20. Prior to the Safety Data Exchange Agreement dated January 28, 2013, Besins and AbbVie's predecessors had Pharmacovigilance Agreements dated July 30, 2003, and amended November 8, 2004 and May 22, 2006. Ex. 8 – 10.

21. Pursuant to the Safety Data Exchange Agreement, Besins S.A. agreed to: "be responsible for detection and evaluation of safety signals" and to "communicate any identified safety signal upon confirmation of the validity of the safety signal." Ex. 7 at XII, p. 9.

22. Besins Healthcare is a "TRT Sponsor" that contributed to the in the "industry briefing book" submitted to the FDA by TRT sponsors in advance of the September 2014 Advisory Committee meeting, which addressed, *inter alia*, the scope of the approved indication for AndroGel, guidelines for prescription of AndroGel, risks associated with testosterone replacement therapy, purported benefits testosterone replacement therapy, and estimated prevalence of hypogonadism. Ex. 11 at 16.

23. The Besins defendants participated in the Advisory Committee convened by the U.S. Food and Drug Administration in September 2014 and hosted at least one event in Herndon, Virginia, that was attended by U.S. testosterone experts known as key opinion leaders ("KOLs") in connection with the FDA Advisory Committee meeting in September 2014. Ex. 12; Ex. 1 at 68:1-14.

24. Besins employees Paul Piette and Jean-Paul Dutret, "medical liaisons" employed by Besins, were in attendance at the FDA Advisory Committee meeting. Ex. 1, Bua Tr. 67:21-69:15. Mr. Piette was "responsible for medical affairs worldwide ex-U.S." and Mr. Dutret was responsible for "worldwide global ex-U.S. pharmacovigilance." Ex.

1 at 69: 6-15. Jay Bua, President of Besins Inc., who also sits on the Board of Directors for Besins S.A. attended the KOL meeting. *Id.* at 68:21-69:5.

25. The Besins defendants had several annual meetings with AbbVie regarding sales of AndroGel in the United States. Ex. 1, Besins 30(b)(6) Tr. at 28:1-29:24; 34:10-54:13; 59:17-64:4; 83:3-10.

26. The Besins defendants have received millions of dollars annually from sales of AndroGel from within the United States. Besins' royalties from U.S. AndroGel sales were:

- 2000 (Q4): \$603,572
- 2001: \$7,815,433
- 2002: \$14,633,736
- 2003: \$22,384,257
- 2004: \$22,922,921
- 2005: \$22,609,778
- 2006: \$26,215,019
- 2007: \$32,250,824
- 2008: \$37,713,200
- 2009: \$48,297,504
- 2010: \$58,038,192
- 2011: \$68,444,275
- 2012: \$90,361,595
- 2013, \$80,061,327
- 2014: \$72,791,626
- 2015: \$28,667,865

Ex. 13; Ex. 1 at 18:14-21:11; and Ex. 2 at 183:8-188:8.

27. AndroGel royalties in the United States have accounted for approximately one-third of Besins' revenues. Ex. 1, Besins 30(b)(6) Tr. at 23:14-26:10.

28. The Besins defendants knew there was insufficient evidence regarding cardiovascular risks associated with AndroGel, but that they should not pursue safety studies and, instead, continue profiting off of AndroGel sales. Ex. 14.

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Respectfully submitted,

/s/ Trent B. Miracle

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Plaintiffs' Co-Lead Counsel *on behalf of*
Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2018, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Brendan A. Smith

Brendan A. Smith